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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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BLACKWELL SANDERS LLP
720 OLIVE STREET
SUITE 2400
ST. LOUIS, MO 63101

EXAMINER	
FETTEROLF, BRANDON J	
ART UNIT	**PAPER NUMBER**
1642	

MAIL DATE	DELIVERY MODE
08/31/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/707,994	ALBERTO ET AL.	
	Examiner	Art Unit	
	Brandon J. Fetterolf, PhD	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 June 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *22-53* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *22-53* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/27/2007 has been entered.

Claims 22-53 are currently pending and under consideration.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 22-39, 43-48 and 50 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The phase "intercalating moiety is configured to insert into the structure of deoxyribonucleic acid" recited in claims 22 and 32 is a relative term which renders the claim indefinite. The phase "intercalating moiety is configured to insert into the structure of deoxyribonucleic acid" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. In the instant case, it is unclear what is encompassed by the phrase "intercalating moiety is configured to insert into the structure of deoxyribonucleic acid". For example, configuring the intercalating moiety to insert into the structure of deoxyribonucleic acid can be reasonably interpreted as by the "hand of man", wherein the intercalating moiety if configured as a salt or designed synthetically so as to insert into the structure of deoxyribonucleic acid. Alternatively, configuring the intercalating moiety to insert into the structure of deoxyribonucleic acid can be reasonably interpreted as the intercalating moiety itself being configured to insert into the structure of deoxyribonucleic acid such as the intercalating moiety being planar and heterocyclic aromatic. For examination purposes, the phase "intercalating moiety is configured to insert into the structure

of deoxyribonucleic acid" will be interpreted as intercalating moiety itself being configured to insert being capable of inserting into the structure of deoxyribonucleic acid such as the intercalating moiety being planar and heterocyclic aromatic, e.g. a structural property of the intercalating moiety.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 51-53 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. THIS IS A NEW MATTER REJECTION.

New claims 51 recite the limitation "chemical moiety" which Applicants contend have support in the specification on page 4, paragraph 0008 and 0010. However, the limitation "chemical moiety" has no clear support in the specification and the claims as originally filed. Applicant is required to cancel the new matter in the response to this Office Action. Alternatively, applicant is invited to provide sufficient written support for the "limitation" indicated above. See MPEP 714.02 and 2163.06

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 22-24, 26-29, 32-37 and 40-53 are rejected under 35 U.S.C. 102(b) as being anticipated by Toner et al. (W0 93/21957, 1993, IDS, of record) as evidenced by Albert et al. (US 5,776,894, 1998, of record).

Toner et al. teach a targeting radioactive immunoreagent comprising a metal radionuclide ion, a complexing agent which is a derivative of phenantroline and an immunoreactive group covalently bonded through a protein reactive group to the complexing agent (page 6, lines 1-10 and page 8, lines 9-13, structure A-IV). With regards to the immunoreactive group, the WO document teaches that the immunoreactive group includes, but is not limited to, antibodies such as B72.3, 9.2.27, D612, UJ13A, NRLU-10, 7E11c5, CC49, TNT, PR1A3, ING-1, B174 and B43 antibodies (page 122). With regards to the metal radionuclide ion, the WO document teaches that the radionuclide ion is ^{90}Y (page 122). In addition to the disclosure of a targeting radioactive immunoreagent, the WO document teaches a diagnostic composition and a therapeutic composition comprising the radioactive immunoreagent, as well as a method of diagnosing and treating a patient using said radioactive immunoreagent (page 122). Specifically, the WO document teaches that the radioactive immunoreagent are used for the diagnosis and treatment of a tumor, wherein the immunoreagent is an antibody specific for a tumor antigen (page 61, lines 21-31). Thus, while Toner et al. do not explicitly teach that ^{90}Y is a γ emitting nuclide, the claimed limitation does not appear to result in a manipulative difference when compared to the prior arts disclosure in because as evidenced by Albert et al.et al., γ emitting nuclides include, but are not limited to, ^{90}Y (column 11, lines 3-8). Thus, while Toner et al. does not explicitly teach that phenantroline is an intercalating moiety configured to insert into the structure of deoxyribonucleotide, due to the indefiteness set forth above, the claimed limitation has been interpreted as a structural property of the intercalating moiety, e.g, planar and heterocyclic aromatic. As such, the phenantroline derivative, which is a planar, aromatic heterocycle meets the claimed limitation. Moreover, even though the claims are drawn to a mechanism by which the intercalating moiety inserts into the deoxyribonucleic acid, the claimed limitation does not appear to distinguish over the prior art teaching of the same or nearly the same compound. The mechanism of action does not have a bearing on the patentability of the invention if the invention was already known or obvious. Mere recognition of latent properties in the prior art does not render nonobvious an otherwise known invention. In re Wiseman, 201 USPQ 658 (CCPA 1979). Granting a patent on the discovery of an unknown but inherent function would remove from the public that which is in the public domain by virtue of its inclusion in, or obviousness from, the prior art. In re Baxter Travenol Labs, 21 USPQ2d 1281 (Fed. Cir. 1991). See M.P.E.P. 2145.

Note: In order to expedite prosecution, the Examiner would like to respond Applicants previous arguments pertaining to the previous rejection over Toner et al. (W0 93/21957, 1993, IDS, of record) as evidenced by Albert et al. (US 5,776,894, 1998, of record) as they relate to the instant rejection. In response to the previous rejection, Applicants assert that the present application is directed to metal complexes having a moiety with an affinity for cancer cells, an intercalating moiety that will insert between the base pairs in a strand of deoxyribonucleic acid, and a metal center bound to the moieties having affinity for cancer cells and the intercalation moiety. With regards to the intercalating moiety, Applicants assert that the most effective characteristics of a DNA intercalation moiety to provide a strong intercalation are planar and aromatic heterocyclic. In contrast, Applicants assert that Toner et al. does not teach or suggest the use of intercalating moieties to insert into the DNA strands of the cancer cells. For example, Applicants contend that while Toner et al. teaches a "metal radionuclide ion, a complexing agent which is pyridine, bipyridine, terpyridine, quaterpyridine, quinuepyridine, seipyridine, or phenanthroline, and an immunoreactive group covalently bonded through a protein reactive group to the complexing agent, Toner specifically describes a large substituents on the complexing agent as a "protein reactive group" which is not designed to insert into the DNA strands as recited in the present claims, but is instead designed to react with "amine or sulfhydryl groups on the protein or biological molecule containing the immunoreactive group. Applicants further assert that although Toner discloses a large class of possible compounds that may be used for the immunoreactive reagent, none of these are disclosed as reacting with DNA. Instead, Applicants assert that the targeting immunoreactive groups of Toner are intended to bring the reagent into the target cells.

These arguments have been carefully considered, but are not found persuasive.

First, the Examiner appreciates Applicants submission of the appropriate case law pertaining to anticipation rejections; and further, a short synopsis of the application and/or invention. However, Applicants have not appeared to establish a patentable difference between the prior art and the claimed invention. For example, Applicants assert that the Toner et al. does not teach or suggest the use of intercalating moieties to insert into the DNA strands of the cancer cells because the protein reactive group on the complexing agent is designed to react with amine or sulfhydryl groups on the protein or biological molecule containing the immunoreactive group. However, the Examiner recognizes that Applicants appear to be misinterpreting the use of the "protein reactive

group". For example, the Examiner recognizes that the protein reactive group on the complexing agents is used in the conjugation step for conjugating the complexing agent to the immunoreactive group. Moreover, the Examiner recognizes that Toner et al. teach complexing agents such as phenantroline which is taught in the instant specification and claimed in the instant application as a intercalating moiety which inserts into the structure of deoxyribonucleic acids. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., immunoreactive reagent reacting with DNA) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). In the instant case, the Examiner recognizes that the claims recite a moiety having affinity for cancer cells which is clearly taught by Toner et al., i.e., immunoreagent is an antibody specific for a tumor antigen (page 61, lines 21-31).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Toner et al. (WO 93/21957, 1993, IDS, of record) in view of Albert et al. (US 5,776,894, 1998, of record).

Toner et al. teach, as applied to claims 22-24, 26-29, 32-37 and 40-42 above, a targeting radioactive immunoreagent comprising a metal radionuclide ion, a complexing agent which is a derivative of phenantroline and an immunoreactive group covalently bonded through a protein reactive group to the complexing agent (page 6, lines 1-10 and page 8, lines 9-13, structure A-IV). With regards to the immunoreactive group, the WO document teaches that the immunoreactive group includes, but is not limited to, antibodies such as B72.3, 9.2.27, D612, UJ13A, NRLU-10, 7E11c5, CC49, TNT, PR1A3, ING-1, B174 and B43 antibodies (page 122). With regards to the metal radionuclide ion, the WO document teaches that the radionuclide ion is ^{90}Y (page 122). In addition to the disclosure of a targeting radioactive immunoreagent, the WO document teaches a

diagnostic composition and a therapeutic composition comprising the radioactive immunoreagent, as well as a method of diagnosing and treating a patient using said radioactive immunoreagent (page 122). Specifically, the WO document teaches that the radioactive immunoreagent are used for the diagnosis and treatment of a tumor, wherein the immunoreagent is an antibody specific for a tumor antigen (page 61, lines 21-31).

Toner et al. do not explicitly teach that the radioactive metal is selected from the group consisting of Tc-99m, Re-186, Re-188 and Mn.

Albert et al. teach somatostatin peptides bearing at least one chelating group with a detectable element, wherein the detectable elements includes, but is not limited to, g-emitting radionuclides such as Tc-99 and Re-186 (abstract and column 11, lines 3-8). Moreover, Albert et al. teach that the somatostatin peptide bearing at least one chelating group with a detectable element are useful for the visualization and treatment of somatostatin receptor positive tumors (column 12, lines 26-35).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to substitute 90Y as taught by Toner et al. for Tc-99 or Re-186 in view the Albert et al teachings that 90Y, Tc-99 and Re-186 are known γ and β emitters As such, one would have been motivated to do so because Albert et al. teach that 90Y, Tc-99 and Re-186 are each γ and β emitters useful for treatment and visualization of tumors. Thus, one of ordinary skill in the art would have a reasonable expectation that by substituting 90Y as taught by Toner et al. for Tc-99 or Re-186 in view the Albert et al, one would achieve a targeted radioactive immunoreagent for the treatment and diagnosis of a tumor.

In response to this rejection, Applicants assert that, as discussed above, Toner does not disclose an intercalating agent. Applicants further assert that while Albert et al. teach a somastatin peptide having a chelating group capable of complexing a metal, Albert et al. does not teach or suggest any compounds "configured to insert into the structure of deoxyribonucleic acid". As such, Applicants assert that neither Toner nor Albert, alone or in hypothetical combination teaches all of the elements of independent claim 22.

These arguments have been carefully considered, but are not found persuasive.

In response to applicant's arguments against the references individually, it must be remembered that the references are relied upon in combination and are not meant to be considered

separately as in a vacuum. It is the combination of all of the cited and relied upon references, which make up the state of the art with regard to the claimed invention. The test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference and it is not that the claimed invention must be expressly suggested in any one or all of the references; but rather the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. In re Keller, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). The examiner recognizes that references cannot be arbitrarily combined and that there must be some reason why one skilled in the art would be motivated to make the proposed combination of primary and secondary references In re Nomiya, 184 USPQ 607 (CPA 1975). However, there is no requirement that an "express, written motivation to combine must appear in prior art references before a finding of obviousness." See Ruiz v. A.B. Chance Co., 357 F.3d 1270, 1276, 69 USPQ2d 1686, 1690 (Fed. Cir. 2004). For example, motivation to combine prior art references may exist in the nature of the problem to be solved (Ruiz at 1276, 69 USPQ2d at 1690) or the knowledge of one of ordinary skill in the ad (National Steel Car v. Canadian Pacific Railway Ltd., 357 F.3d 1319, 1338, 69 USPQ2d 1641, 1656 (Fed. Cir. 2004)). References are evaluated by what they suggest to one versed in the art, rather than by their specific disclosures. In re Bozek, 163 USPQ 545 (CCPA 1969). In the instant case, the Examiner recognizes that the Toner et al. teaches a targeting radioactive immunoreagent comprising a metal radionuclide ion, a complexing agent which is a derivative of phenantroline and an immunoreactive group covalently bonded through a protein reactive group to the complexing agent, but does not explicitly teach that the radionuclide is selected from the group consisting of Tc-99m, Re-186, Re-188 and Mn. However, Albert et al. teach somatostatin peptides bearing at least one chelating group with a detectable element, wherein the detectable elements includes, but is not limited to, g-emitting radionuclides such as Tc-99 and Re-186. As such, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to substitute 90Y as taught by Toner et al. for Tc-99 or Re-186 in view the Albert et al teachings that 90Y, Tc-99 and Re-186 are known γ and β emitters As such, one would have been motivated to do so because Albert et al. teach that 90Y, Tc-99 and Re-186 are each γ and β emitters useful for treatment and visualization of tumors. Thus, one of ordinary skill in the art would have a reasonable expectation that by substituting 90Y as taught by Toner et al. for Tc-99 or Re-186 in view

the Albert et al, one would achieve a targeted radioactive immunoreagent for the treatment and diagnosis of a tumor.

Claims 30-31 and 38-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Toner et al. (W0 93/21957, 1993, IDS, of record) in view of Holley et al. (Cancer Research 1992; 52: 4190-4195, of record).

Toner et al. teach, as applied to claims 22-24, 26-29, 32-37 and 40-53 above, a targeting radioactive immunoreagent comprising a metal radionuclide ion, a complexing agent which is a derivative of phenantroline and an immunoreactive group covalently bonded through a protein reactive group to the complexing agent (page 6, lines 1-10 and page 8, lines 9-13, structure A-IV). With regards to the immunoreactive group, the WO document teaches that the immunoreactive group includes, but is not limited to, antibodies such as B72.3, 9.2.27, D612, UJ13A, NRLU-10, 7E11c5, CC49, TNT, PR1A3, ING-1, B174 and B43 antibodies (page 122). With regards to the metal radionuclide ion, the WO document teaches that the radionuclide ion is ^{90}Y (page 122). In addition to the disclosure of a targeting radioactive immunoreagent, the WO document teaches a diagnostic composition and a therapeutic composition comprising the radioactive immunoreagent, as well as a method of diagnosing and treating a patient using said radioactive immunoreagent (page 122). Specifically, the WO document teaches that the radioactive immunoreagent are used for the diagnosis and treatment of a tumor, wherein the immunoreagent is an antibody specific for a tumor antigen (page 61, lines 21-31).

Toner et al. do not explicitly teach that tumor seeking molecule is spermidine.

Holley et al. teach a method of targeting chlorambucin to a tumor cell by conjugating chlorambucin to spermidine (page 4191, 1st column, 1st full paragraph). In particular, the reference teaches that the chlorambucin-spermidine conjugate showed greater anti-tumor activity both in vivo and in vitro compared to chlorambucin due to increased tumor uptake and increased affinity for DNA (page 4194, 2nd column, last paragraph)

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to modify the conjugate taught by Toner et al. with a spermidine in view of the teachings Holley et al.. One would have been motivated to so because Holley et al. teach that spermidine conjugates show increase tumor uptake and increased affinity for DNA. Thus, one of

ordinary skill in the art would have a reasonable expectation of success that by modifying the conjugate taught by Toner et al. with a spermidine in view of the teachings Holley et al, one would achieve a targeted radioactive immunoreagent for the treatment and diagnosis of a tumor.

In response to this rejection, Applicants assert that, as disclosed above, Toner does not disclose an intercalating agent. Applicants further assert that Holley teaches a compound that cross-links DNA which different from the instant invention which is through DNA intercalation. Moreover, Applicants assert that the cross-linking agents disclosed by Holley would provide an opposite effect to that of the radionucleotide of Toner which would break a DNA strand. As such, neither Toner nor Holley, alone or in hypothetical combination, teaches all of the claimed limitations.

These arguments have been carefully considered, but are not found persuasive.

In response to applicant's arguments against the references individually, it must be remembered that the references are relied upon in combination and are not meant to be considered separately as in a vacuum. It is the combination of all of the cited and relied upon references, which make up the state of the art with regard to the claimed invention. The test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference and it is not that the claimed invention must be expressly suggested in any one or all of the references; but rather the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. In re Keller, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). The examiner recognizes that references cannot be arbitrarily combined and that there must be some reason why one skilled in the art would be motivated to make the proposed combination of primary and secondary references In re Nomiya, 184 USPQ 607 (CPA 1975). However, there is no requirement that an "express, written motivation to combine must appear in prior art references before a finding of obviousness." See Ruiz v. A.B. Chance Co., 357 F.3d 1270, 1276, 69 USPQ2d 1686, 1690 (Fed. Cir. 2004). For example, motivation to combine prior art references may exist in the nature of the problem to be solved (Ruiz at 1276, 69 USPQ2d at 1690) or the knowledge of one of ordinary skill in the ad (National Steel Car v. Canadian Pacific Railway Ltd., 357 F.3d 1319, 1338, 69 USPQ2d 1641, 1656 (Fed. Cir. 2004)). References are evaluated by what they suggest to one versed in the art, rather than by their specific disclosures. In re Bozek, 163 USPQ 545 (CCPA 1969). In the instant case, the Examiner recognizes that the Toner et al. teaches a targeting radioactive

immunoreagent comprising a metal radionuclide ion, a complexing agent which is a derivative of phenantroline and an immunoreactive group covalently bonded through a protein reactive group to the complexing agent, but does not explicitly teach that the tumor seeking molecule is spermidine. However, Holley et al. teach a method of targeting chlorambucin to a tumor cell by conjugating chlorambucin to spermidine (page 4191, 1st column, 1st full paragraph). Thus, Holley et al. teaches spermidine as a targeting moiety. It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to modify the conjugate taught by Toner et al. with a spermidine in view of the teachings Holley et al.. One would have been motivated to so because Holley et al. teach that spermidine conjugates show increase tumor uptake and increased affinity for DNA. Thus, one of ordinary skill in the art would have a reasonable expectation of success that by modifying the conjugate taught by Toner et al. with a spermidine in view of the teachings Holley et al, one would achieve a targeted radioactive immunoreagent for the treatment and diagnosis of a tumor.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 22 and 32 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,844,425.

Although the conflicting claims are not identical, they are not patentably distinct from each other because a species anticipates a genus.

The "species" compound comprising: (a) a biomolecule selected from somatostatin, neurotensin, bombesin-receptor binding molecules, antibodies, antennapedia peptide, and molecules binding to GPIIb/GPIIIa receptors; coupled to (b) an aromatic intercalating moiety with binding affinity for double-stranded DNA selected from acridine, porphyrin, ellipticine, phenantroline, carbazole, benzimidazole, and tetracycline compounds with cytostatic activity; which is complexed to (c) a .gamma.-emitting radioactive metal selected from Tc-99m, Re-186, Re-188, and Mn, wherein said compound is associated with one or more pharmaceutically acceptable excipients claimed in the conflicting patent appears to fall within the same scope as the genus of compounds comprising (a) a tumor-seeking biomolecule; coupled to (b) an aromatic intercalating moiety with binding affinity for double-stranded DNA selected from the group consisting of acridine, porphyrin, ellipticine, phenantroline, carbazole, benzimidazole, and tetracycline compounds with cytostatic activity; which is complexed to a metal compound claimed in the instant application being examined.

In response to this rejection, Applicants request that the Examiner hold in abeyance the double-patenting rejection until the present claims are determined to be allowable at which time a terminal disclaimer may be filed.

Thus, the Examiner maintains the obviousness-type double patenting rejection.

Therefore, No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brandon J. Fetterolf, PhD whose telephone number is (571)-272-2919. The examiner can normally be reached on Monday through Friday from 7:30 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shanon Foley can be reached on 571-272-0898. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Brandon J Fetterolf, PhD
Patent Examiner
Art Unit 1642

BF